

LET/25/KH/38883  
17 June 2025



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## CropLife Europe June 2025 key concerns on CRA EFSA Cookbook and IESTI methodology

*CropLife Europe input for SCOPAFF Residues meeting 23-24 June 2025*

- **Cumulative Risk Assessment**
- **Other approaches for risk assessment (IESTI)**

CropLife Europe would like to share our views on two agenda items ahead of the Standing Committee on Plants, Animals, Food and Feed (Section Phytopharmaceuticals – Pesticide Residues) to be held on 23-24 June. These items are A.09 – Cumulative Risk Assessment and A.10 Other approaches for risk assessment (IESTI, PRIMo).

### A.09 – Cumulative Risk Assessment

During the EFSA Webinar (Open MCRA tool for prospective cumulative risk assessment (pCRA)) in May, EFSA indicated that a decision to hold a public consultation on the EFSA “Cookbook” would be made by risk managers. Following the meeting between CLE and DG SANTE on 3<sup>rd</sup> of February, we understood that this was likely and we welcomed the opportunity and the transparency of the process. In subsequent discussions with EFSA we now understand that an alternative approach, to publish/implement the cookbook as a living document, and review/consult on this after a defined period of time (possibly one year) may also be an option.

As a key stakeholder in the implementation and use of pCRA, CLE would like to reiterate our willingness to contribute to a consultation ahead of implementation. As you are aware, CLE have commissioned two projects to review the current tools and methodologies and have gained useful insights, which we have been able to share with RIVM to help support improvements in the modelling. **We therefore kindly request that risk managers prioritise a consultation ahead of the implementation of the “Cookbook”** and we commit to providing robust and relevant input into this process.

### A.10 – Other approaches for risk assessment (IESTI)

CLE understands the risk communication need to use the MRL as the input value for the EU IESTI. It is true that only Option 1 (proposed in the EFSA Review of IESTIs (2025)) currently offers this, and this option also reflects the general position following the [EFSA/WHO \(2015\) IESTI Workshop](#). Concerns at that time over the reliability of the available unit weight (UW) data led to a recommendation to remove the UW concept from the calculations.

However, since EFSA re-evaluated newer UW data for [PRIMo 4](#) these concerns have been addressed. **Therefore, CLE strongly support Option 3, which retains the UW concept, yet with some modifications.**

Currently, in Option 3 the HR (cases 1 and 2) is replaced by the P95 derived from the OECD MRL calculator. However:

- *where residue definitions for monitoring and risk assessment are aligned:*

from a risk communication perspective, it may be more appropriate to calculate the IESTI based on the proposed/applicable MRL, whilst retaining the UW concept. For case 3 commodities (processed commodities that are bulked or blended), where use of the MRL adds excessive conservatism, we propose an additional bulking/blending factor.

- *where residue definitions for monitoring and risk assessment differ:*

use of the median conversion factor (CF) proposed by EFSA may not be scientifically robust as it may not adequately represent the relative levels of the different residue components at the upper end of the residue distribution (i.e. a high parent residue may correspond to less metabolism). Therefore, CLE propose the calculation of a "risk assessment MRL" from the P95 of the risk assessment residue values, using the same rounding approach/factor applied to the unrounded MRL to derive the rounded MRL.

CropLife Europe would be happy to provide more details of these proposals.

Yours sincerely



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cc. María Tabernero (EC – DG SANTE)  
Silvia Nicolau-Solano (EC – DG SANTE)

*This letter will be published on the CropLife Europe website and will be available at:*  
<https://croplifeeurope.eu/resources-library/>

